Public Health Service
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

Via Federal Express 4165 0459 5698

Our Reference: 2911743

September 15, 2000

Paul Carter, CEO
Foster Farms
843 Davis Street
Livingston, California 95334

WARNING LETTER

Dear Mr. Carter:

An inspection of your medicated feed manufacturing facility Del Mesa Farms, 3600 West Main, Turlock, California, 95380, on August 2 through 8, 2000, by Food and Drug Administration (FDA) Investigator Thomas W. Gordon revealed significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (Title 21 Code of Federal Regulations (21 CFR), Part 225). Such deviations cause the medicated feeds manufactured at your mill to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act. The deviations found during the inspection are as follows:

> You are failing to sequence, flush, or otherwise physically clean your manufacturing and delivery equipment between batches of medicated feed to ensure that cross contamination does not occur. For example, on 8-2-00, you manufactured a turkey feed containing Halofuginone hydrobromide (trade name Stenorol), Production Order #18161. Immediately following that production run, you manufactured a turkey finisher feed, Production Order #18162. There was no flush, sequence, or any adequate cleanout between these two production runs of feed.
>
> You are flushing medicated feed with a medicated flush, thereby causing illegal combinations of veterinary feed drugs to occur. For example, on 8-1-00, you produced a feed containing Sulfadimethoxine and Ormetoprim (trade name

Rofenaid 40), Production Order #18127. You followed that medicated feed with a medicated flush containing Bacitracin Methylene Disalicylate (trade name BMD 50), Production Order #18128. The medicated feed containing Sulfadimethoxine and Ormetoprim was combined with the medicated flush containing Bacitracin Methylene Disalicylate. This drug combination is not approved for turkeys or any other species per 21 CFR 558.76 and 558.575. The use of the above drug combination in the listed feeds causes the feeds to become adulterated within the meaning of Section 501(a)(6), because they are unsafe within the meaning of Section 512(a)(l)(A) of the Act.

You are failing to perform adequate numbers of assays for Sulfadimethoxine and Ormetoprim (trade name Rofenaid 40). For feeds requiring a medicated feed mill license, three samples must be taken and analyzed at periodic intervals during the calendar year.

You are failing to investigate and implement corrective action after finding that a medicated feed is not within specifications following assay. For example, four assays conducted in 1999 for Bambermycin (trade name Flavomycin), Coban (trade name Monensin), and Bacitracin Methylene Disalicylate (trade name BMD 50) were out of specification. There was no documented investigation or corrective action implemented as a result of these failures.

You are failing to proofread, date, and sign or initial by a responsible individual incoming master formulas prior to beginning manufacture of these feeds. For example, on 7-3-00, your firm approved the formula #1840, revision 55. But you produced a feed using this formula on 7-2-00.

You are failing to list the drug ingredient Bacitracin Methylene Disalicylate, when you use it in combination with Sulfadimethoxine and Ormetoprim. The use of this label causes the feed to be misbranded within the meaning of Section 502(e)(l)(A)(i) of the Act, because it fails to bear the established name of the drug active ingredient.

Causing the adulteration of drugs after receipt in interstate commerce and delivering for introduction into interstate commerce of any article in violation of Section 512 are violations of Sections 301(k) and 301(a) of the Act, respectively.

You should take prompt action to correct these CGMP violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these CGMP violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction, and/or notice of opportunity for a hearing on a proposal to withdraw approval of your Medicated Feed

Mill License per Section 512(m)(4)(B)(ii) of the Act and 21CFR Part 514.115(c)(2). (This letter constitutes official notification under the law.)

Based on the results of the August 2 through 8, 2000, inspection, evaluated together with the evidence before FDA when your Medicated Feed Mill License was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feeds are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

Until the CGMP violations have been corrected and the corrections verified by FDA, the Center for Veterinary Medicine will not approve medicated feed applications for your facility.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act are being met.

This is your third notification since May 2000, that your firm has been in violation of Good Manufacturing Practices, specifically a lack of adequate cleanout, at your plants. And this is the second time since May 2000, that your firm has been notified of a lack of required number of assays for feeds as required by 21 CFR 225.58. Your firm was notified by Warning Letter, dated May 26, 2000, of violations at your Foster Farms Feed Mill, Burrell, CA. These violations included failing to sequence, flush, or otherwise physically clean the manufacturing and delivery equipment between batches of medicated feed; and a failure to take the required number of assays for Sulfadimethoxine and Ormetoprim (trade name Rofenaid 40). An inspection of your Foster Farms Commodities Division, Kingsburg, California, dated July 27 through 31, 2000, found that your firm was failing to sequence, flush, or otherwise physically clean your manufacturing and delivery equipment, or to document such sequencing, flushing, or physically cleaning of their manufacturing and delivery equipment between batches of medicated feed and non-medicated feed. You have failed to take adequate corrective action. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation

demonstrating that corrections have been made. Please direct your reply to Thomas W. Gordon, CSO, 2202 Monterey Avenue, Suite 104E, Fresno, California, 93721.

Sincerely yours,

Kris A. Foster
Acting Director
San Francisco District

cc: [redacted]